Standardized Versus Tailored Implementation of Measurement-Based Care for Depression

Protocol Number: 1R01MH103310-01A1

National Clinical Trial (NCT) Number: NCT02266134

Principal Investigator: Cara C. Lewis, PhD

Affiliation: Kaiser Permanente

Sponsor: Indiana University

Funded by: National Institute of Mental Health (NIMH)

IRB Approval Status: Approved

4 May 2017

Client Informed Consent Document: pages 2-4

Therapist Informed Consent Document: pages 5-8

Protocol 1407578183 IRB Approved

Dear Centerstone Client,

You are invited to participate in a research study. The study is about therapist use of measurement-based care (MBC). MBC uses surveys to help therapists measure patients' symptoms of depression. This helps therapists make decisions about treatment. The study is being conducted by Dr. Cara Lewis in the department of Psychological and Brain Sciences at Indiana. It is funded by the National Institute of Mental Health (R01 MH103310-01A1). A description of this study will be available on http://www.ClinicalTrials.gov, as required by
U.S. Law. This website will not include information that can identify you. At most, the website will include asummary of the results.

You received this form because you agreed to participate in this study. A Centerstone Research InstituteResearch Assistant (RA) called you and you told him/her that you wanted to participate.

TO CONFIRM YOUR FULL PARTICIPATION:

- Read the form included in this envelope. To ask questions, call your local Centerstone RA.
  - Indiana: 812-276-09070
  - Tennessee: 615-483-0076
- Sign and date the form. Send it back in the envelope we provided or bring it to your next Centerstoneappointment.

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COMPENSATION:
You will get a $5 gift card for doing the Baseline Patient Health Questionnaire (PHQ-9) phone interview. Returnyour signed form. You will then get another $15. If we do not get your signed form, then you won't be able to doall the parts of the study. You will not be able to earn more money. Study activities and incentives are summarized below:

Activity	Incentive
• Brief (5-minute) phone survey after each of your normal therapy sessions for 12 weeks	$5 per survey up to $50
• Baseline PHQ-9 phone interview	$20 (mentioned above)
• 12-week PHQ-9 phone interview	$20

PROCEDURES FOR THE STUDY You will be asked to do the following things:
1. Answer questions on the phone.
2. Allow Centerstone to share de-identified information for research purposes ONLY.
3. Answer questions on and related to the PHQ-9 during session and via phone-based surveys.

1. You were asked to respond to a Client Demographics Survey and the PHQ-9 on the phone. These surveys tookabout 10-20 minutes to complete. You will be asked to complete the PHQ-9 again in three months.

2. You will be asked to allow certain information to be used for research . The information is described in theCenterstone Authorization for the Release of Health Information for Research form.

3. During your treatment, you may be asked to fill out the PHQ-9 before your therapy sessions at Centerstone. The PHQ-9 will take about five to ten minutes to complete. Your therapist may use the PHQ-9 to understand yourdepression symptoms. You will be asked to respond to a phone survey after each therapy session to see if your therapist discussed the PHQ-9 with you. This survey will take a few

minutes to complete.

****IMPORTANT****
The phone survey uses an automated phone system. When the system calls, the phone number will be the same asthe number of the RA whom did your first phone survey. Please save the RA's number into your contacts so you know that the automated phone system is calling. Please look at the reminder card in this envelope for important information.

CONFIDENTIALITY
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. We will use a 9-digit anonymous identification (ID) number to identify your surveys. Your identity will be confidential in study reports and result databases. Only research staff trained in confidentiality will access your surveys and transcribe audio recorded interviews and meetings. All identifiers will be removed atthe time of the transcription and replaced with your anonymous ID. All data will be stored in locked files.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis includegroups such as the study investigator and his/her research associates, the Indiana University Institutional ReviewBoard or its designees, the study sponsor (NIMH), and (as allowed by law) state or federal agencies, specificallythe Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH).

CERTIFICATE OF CONFIDENTIALITY
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institute of Health. We can use this to legally refuse to disclose information that may identify you in any federal, state, local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demandsfor identifying information. The Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others.

You should understand that this Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medicalcare provider, or other person obtains your written consent to receive research information, then the Certificate will not be used to withhold that information. The link between your research number and your name is held by the research team and is a part of the confidential research record.

CONTACTS FOR QUESTIONS OR PROBLEMS
If you have questions you can contact:

- Dr. Cara Lewis at Indiana University, 812-855-6952
- Centerstone Research Institute RA, Indiana: 812-276-9070
- Centerstone Research Institute RA, Tennessee: 615-483-0076

If you have questions about your rights as a research participant or to discuss problems, complaints or concernsabout a research study, or to obtain information, or offer input, contact:

- IU Human Subjects Office or (812) 856-4242 or by email at irb@iu.edu.

VOLUNTARY NATURE OF STUDY
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study or failing to answer all of the questions asked will not result in any penalty or loss of benefits towhich you are entitled. Your decision whether or not to participate will not affect your current or future relations with Centerstone in any way. If new information becomes available that may affect the risks or benefits of this study, you will be notified so that you can decide whether or not you would like to continue participation.

SUBJECT'S CONSENT
I have given my verbal consent to participate in this research study. I have this printed a copy of the informedconsent document to keep for my records.

Form date: May 4th, 2017

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Standardized versus Tailored Implementation of Measurement Based Care for Depression Clinician Version

NIMH Grant Number: R01 MH103310-01A1

You are invited to participate in a research study to evaluate a standardized versus tailored implementation of measurement-based care, which is the practice of using symptom measurement to inform mental health care, for depression. You were selected as a possible subject because you are a clinician at Centerstone who is actively treating clients with depression in individual psychotherapy and we hope the implementation of measurement-based care will maximize your efficiency in therapy and improve patient care. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Cara Lewis in the department of Psychological and Brain Sciences at Indiana University. It is funded by the National Institutes of Mental Health (R01 MH103310-01A1). A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results.

STUDY PURPOSE
The purpose of this study is to test a standardized versus a tailored approach to implementing measurement-based care at Centerstone. Measurement-based care is the practice of using symptom measurement to inform mental health care and will serve as a way for you as a clinician to track client progress throughout treatment. Recent research has demonstrated a need to adapt evidence-based practices like measurement-based care to fit the needs of clinicians across different mental health organizations. We hope to compare these two approaches to determine which approach (standardized versus tailored) is superior with the goal of identifying a generalizable and practical way of bringing measurement based care to community mental health centers providing treatment to adults with depression.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:
If you agree to participate, you will be one of 150 clinicians from 12 participating Centerstone sites who will be participating in this research.

PROCEDURES FOR THE STUDY:
If you agree to be in the study, you will be asked to do the following things:

You will be asked to complete a series of surveys regarding your background, your experiences at Centerstone and with Centerstone leadership, and your opinions about measurement-based care. You will be asked to allow the research staff to use your de-identified survey responses for the purposes of research. You will be asked to complete the questionnaires described above (background, Centerstone, Centerstone leadership, and opinions about measurement-based care) on three separate occasions during your study participation (at the beginning of the 5-month active implementation period, the end of the 5-month active implementation, and 10 months following the active implementation period). All questionnaires will be completed online using assessment software or via hard copy (in-person). You will be emailed a link or provided hard copy assessments of the questionnaires at each assessment point. These questionnaires should take approximately 60 minutes to complete either on at work or on your own time, whichever you prefer.

You may be asked to participate in a1.5 hour focus group during the first month of the 5-month active

implementation phase, at the end of the 5-month active implementation, and/or during the post-implementation/sustainment phase. The 1.5 hour focus group will occur during work hours and will help the clinic directors to understand perceived barriers to measurement-based care implementation, opinions about the functionality of the measurement-based care, and also general clinician needs and values. The focus group will be held at your workplace during working hours. This focus group will be audiotaped so that the discussion can be transcribed to allow the content to be reviewed by the implementation team to inform measurement-based care implementation. If you choose to participate in the research then this transcribed, de-identified content will be coded and analyzed for research.
You may also be asked to participate in an individual exit interview at the end of the 5-month active implementation period regarding your views about and use of the PHQ-9. This interview will take about an hour. Additionally, you may be asked to participate in a 30 minute Contamination Interview at 2 time points during the sustainment period (between 10 and 15 months, after the active implementation). These interviews will be audiotaped so that it can be transcribed. If you choose to participate in the research then this transcribed, de-identified content will be coded and analyzed for research.

Based upon survey and the needs assessment results prior to use of measurement-based care, one opinion leader and one self-nominated measurement-based care champion (the opinion leader could also be the measurement-based care champion, but in some cases this will be two different people) will be invited to join an implementation team. The implementation team will consists of research team members, site administrator, a client, an office professional, and 2-4 clinician opinion leader and champion. If you are chosen as an opinion leader or if you self-nominate yourself as a measurement-based champion, you will be asked to participate in one-hour triweekly meetings across the first five months of measurement-based care implementation and you will be encouraged to meet without the research staff during the 10 months following measurement-based care implementation to facilitate identification of additional barriers to the implementation process or to promote fidelity to measurement-based care (depending on the condition to which you are randomly assigned; tailored versus standardized, respectively). All meetings held during the 5-month implementation period and the 10 month follow up period will be audio-recorded to allow the research team to code implementation barriers and the purpose of the meetings. You will be reminded at the beginning of each meeting not to use client names during the discussion to protect client confidentiality. Audio-recorded sessions will be transcribed using and coded by research staff or via a VoiceBase, Inc. a voice transcription and indexing company. None of your identifying information will be retained in the transcripts and only anonymous identification numbers will be used. Before each implementation team, you may also have the option of completing a structured consultation form, which will aid in an organized discussion of specific consultation issues related to measurement-based care. This form will be collected to allow the research team to code for implementation barriers and purpose of the meeting. None of your identifying information will be gathered on this form. If you participate on the implementation team, you will be asked to complete a small battery of questionnaires in-person regarding your experience with the implementation team that will take about 25 minutes to complete at two time points (5-months and 15-months).

You will be asked to participate in one four-hour training session that will introduce either the standardized measurement-based care approach or the tailored measurement-based care procedures. This training will take place at your workplace and will be conducted by members of the implementation and/or research teams. You will be asked to complete a small battery of questionnaires immediately following the training to help the researchers understand your training experience. Completing the questionnaires will take about 20-25 minutes.

You will be asked to allow your job category/title, licensure, supervisor information and demographics to be retrieved from Centerstone records to obtain information about clinician experience.

You may be asked to allow your sessions with your depressed clients to be audiorecorded. These tapes would be reviewed and coded by an objective team of researchers to understand how measurement-based

care is used in the community and to improve our understanding of how to help clients using measurement-based care. Only a subsample of your audiotaped sessions would be reviewed and coded and these tapes will be randomly selected.

RISKS OF TAKING PART IN THE STUDY:
While participating in the study, potential risks include:

- Potential breach of confidentiality with respect to therapist names collected on the consent form. Every effort to ensure confidentiality will be made by Indiana University Research staff, and all questionnaires collected throughout the study protocol will be identified using an anonymous 6-digit ID rather than names.
- Potential discomfort from sharing opinions on study questionnaires or in focus groups. However, this potential discomfort may still be present even if you decide not to allow your responses to be used for research. You may also choose to withdraw your consent from the study at any time without penalty and without harm to your status as a clinician at Centerstone. Centerstone staff will not be informed as to who agreed to have their information used for general research purposes.
- Potential to perceive coercion to participate in the study given that this proposal aligns with the agency's overall strategic goals. You are not obligated to participate in the research and participation in the research will not be criteria for adjustment of wages or job position.

BENEFITS OF TAKING PART IN THE STUDY:
The benefits to participation in this study include the opportunity to receive training in the use of measurement-based care, an evidence-based practice framework. This training opportunity may enable you to enhance your client care by providing you with an additional tool for monitoring client progress throughout treatment and for assessing client treatment outcomes. In addition, you may benefit from the enhanced Electronic Health Record system equipped with the PHQ-9 and a clinician-informed optimal user interface.

ALTERNATIVES TO TAKING PART IN THE STUDY:
Instead of being in the study, you have the option to not participate in the study. Choosing not to participate in the study will not affect your standing as a clinician at Centerstone.

CONFIDENTIALITY
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Survey responses will be identifiable only through an anonymous 6-digit ID across phases that will be used on all questionnaires completed. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. Audio recordings of focus groups, consultations, and training workshops will be transcribed by research staff members trained in confidentiality procedures by the PI or via a voice transcription and indexing company, VoiceBase, Inc. All identifiers will be removed at the time of the transcription and replaced with an arbitrary number. VoiceBase, Inc. provides a human transcription service for audio recordings. This company follows a strict privacy policy that attempts to maintain the utmost confidentiality of all transcriptions. All audiorecordings and data will be stored in locked files.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor (National Institute of Mental Health), and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH).

PAYMENT
You will receive payment for taking part in this study. You will be receive $50 per assessment completed across three time points (three time points: beginning of the 5-month active implementation period, the end of the 5-month active implementation, 10 months following the active implementation period) for the time required to complete the questionnaires and for allowing us to utilize your data for the purposes of research. You will receive $15 at 5-months for assessments completed and $15 at 15 months ($10 if you participate in consultation sessions rather than IT meetings) for the time required to complete the questionnaires and allowing us to utilize your data for the purposes of research. You will receive $25 per focus group if you are asked to participate in the 1.5 hour focus group, which will be held three times during the study (baseline needs assessment, the end of the 5-month active implementation, and implementation team review post-implementation/sustainment). You receive $20 for participation in the exit interview if you are invited to participate, which will be held at the end of the 5-month active implementation period. You will receive $30 each time you participate in the Contamination Interview. You will receive commensurate Continuing Education Units and productivity coverage credit for attending the four hour training and $10 for completing the battery of questionnaires following the training and allowing us to utilize your data for the purposes of research.

CONTACTS FOR QUESTIONS OR PROBLEMS
For questions about the study, contact the researcher Dr. Cara Lewis at Indiana University (812-855-6952).

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (812) 856-4242 or by email at irb@iu.edu.

VOLUNTARY NATURE OF STUDY
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Centerstone in any way.

SUBJECT'S CONSENT
In consideration of all of the above, I give my consent to participate in this research study. I have printed a copy of this informed consent document to keep for my records. By proceeding to the next step of the study (i.e., completing the baseline battery of questionnaires), it is considered implicit consent and I am agreeing to participate in the research study.

Form date: January 2nd, 2017